Claims:

1. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of a pharmaceutically acceptable salt of bupropion, and conventional excipients;

(ii) a first control-releasing coat surrounding said core; and

(iii) a moisture barrier surrounding said first control-releasing coat,

wherein the modified-release tablet is bioequivalent and exhibits a dissolution profile such that after about 2 hours no more than about 20% of the bupropion content is released, after about 4 hours about 15% to about 45% of the bupropion content is released, after about 8 hours about 40% to about 90% of the bupropion content is released and after about 16 hours no less than about 80% of the bupropion content is released.

2. (Original) The modified-release tablet of claim **1** wherein said moisture barrier does not function as an enteric coating as defined by a USP test which requires for an enteric layer-coated tablet, when placed in 0.1N HCl for one hour, that the total amount of the drug released from the core does not exceed 10% and not less than 75% of the drug is released at 45 minutes in pH 6.8 buffer.

3. (Amended) The modified-release tablet of claim **2 [or 3]** when said moisture barrier is comprised of an enteric polymer, a plasticizer and a permeation enhancer.

4. (Amended) The modified-release tablet of claim **2 [or 3]** wherein the application of the moisture barrier to the control-releasing coated tablet results in a total weight gain of no more than about 6% relative to the dry tablet weight.

5. (Original) The modified-release tablet of claim **2** wherein the application of the moisture barrier to the control-releasing coated tablet results in a total weight gain of no more than about 2.5% relative to the dry tablet weight.

6. (Original) The modified-release tablet of claim **3** wherein the enteric polymer is an acrylic polymer.

7. (Original) The modified-release tablet of claim **6** wherein said acrylic polymer is a methacrylic acid copolymer type C.

8. (Original) The modified-release tablet of claim **3**, which comprises about 150mg of said pharmaceutically acceptable salt of bupropion, and the amount of said enteric polymer ranges from 1% to 3% of the dry tablet weight and comprises 55% to 70% of the moisture barrier dry weight.

9. (Original) The modified-release tablet of claim **3**, which comprises about 300mg of said pharmaceutically acceptable salt of bupropion, and the amount of said enteric polymer ranges from 1.5% to 3.0% of the dry tablet weight and comprises from 30% to 90% of the moisture barrier dry weight.

10. (Original) The modified-release tablet of claim **8** wherein said enteric polymer is a methacrylic acid copolymer type C.

11. (Original) The modified-release tablet of claim **9** wherein said enteric polymer is a methacrylic acid copolymer type C.

12. (Original) The modified-release tablet of claim **10** wherein the polymer is Eudragit L 30 D-55.

13. (Original) The modified-release tablet of claim **11** wherein said polymer is Eudragit L 30 D-55.

14. (Amendedl) The modified-release tablet of ~~any one of claims 1-13~~ claim 1 wherein said tablet exhibits a dissolution profile such that after about 2 hours about 2% to about 18% of the bupropion content is released, after about 4 hours about 21% to about 37% of

the bupropion content is released, after about 8 hours about 60% to about 85% of the bupropion content is released and after about 16 hours no less than about 93% of the bupropion content is released.

15. (Original) The modified-release tablet of claim **14** wherein said tablet exhibits a dissolution profile such that after about 2 hours about 4% to about 8% of the bupropion content is released, after about 4 hours about 28% to about 34% of the bupropion content is released, after about 8 hours about 68% to about 74% of the bupropion content is released and after about 16 hours no less than about 96% of the bupropion content is released.

16. (Original) The modified-release tablet of claim **15** wherein said tablet exhibits a dissolution profile such that after about 2 hours about 5% of the bupropion content is released, after about 4 hours about 32% of the bupropion content is released, after about 8 hours about 74% of the bupropion content is released and after about 16 hours no less than about 99% of the bupropion content is released.

17. (Original) The modified-release tablet of claim **16** wherein said pharmaceutically acceptable salt of bupropion is bupropion hydrochloride.

18. (Original) The modified-release tablet of claim **17** wherein said bupropion is present at least about 94% by weight of the core.

19. (Amended) The modified-release tablet of ~~any one of claims **1-18**~~ claim 1 wherein said conventional excipients further comprise a binder and a lubricant.

20. (Original) The modified-release tablet of claim **19** wherein said binder is present from about 1% to about 6% by weight of the core dry weight.

21. (Original) The modified-release tablet of claim **20** wherein said binder is present at about 3% by weight of the core dry weight.

22. (Original) The modified-release tablet of claim **21** wherein said binder is selected from the group consisting of modified starch, gelatin, polyvinylpyrrolidone, cellulose derivatives, polyvinyl alcohol and any combination thereof.

23. (Original) The modified-release tablet of claim **22** wherein said binder is polyvinyl alcohol.

24. (Original) The modified-release tablet of claim **19** wherein said lubricant is present from about 1% to about 6% by weight of the core dry weight.

25. (Original) The modified-release tablet of claim **24** wherein said lubricant is present at about 3% by weight of the core dry weight.

26. (Original) The modified-release tablet of claim **25** wherein said lubricant is selected from the group consisting of glyceryl behenate, stearic acid, hydrogenated vegetable oils and any combination thereof.

27. (Original) The modified-release tablet of claim **26** wherein said lubricant is glyceryl behenate.

28. (Amended) The modified-release tablet of ~~any one of claims 1-27~~ claim 1 wherein said control-releasing coat consists essentially of a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer.

29. (Original) The modified-release tablet of claim **28** wherein said water-insoluble water-permeable film forming polymer is present at about 35% to about 60% by weight of said control-releasing coat dry weight.

30. (Original) The modified -release tablet of claim **29** wherein said water-insoluble water-permeable film forming polymer is present at about 50% by weight of said control-releasing coat dry weight.

31. (Original) The modified-release tablet of claim **30** wherein said water-insoluble water-permeable film forming polymer is present at about 45% by weight of the tablet dry weight.

32. (Original) The modified-release tablet of claim **31** wherein said water-insoluble water-permeable film forming polymer is selected from the group consisting of a cellulose ether, a cellulose ester, polyvinyl alcohol and any combination thereof.

33. (Original) The modified-release tablet of claim **32** wherein said water-insoluble water-permeable film forming polymer is a cellulose ether.

34. (Original) The modified-release tablet of claim **33** wherein said cellulose ether is selected from the group consisting of ethyl cellulose grade PR100, ethyl cellulose grade PR20 and any combination thereof.

35. (Original) The modified-release tablet of claim **34** wherein said cellulose ether is ethyl cellulose grade PR100.

36. (Amended) The modified-release tablet of ~~any one of claims **28-35**~~ claim 28 wherein said plasticizer is present from about 6% to about 30% by weight of said control-releasing coat dry weight.

37. (Original) The modified-release tablet of claim **36** wherein said plasticizer is present at about 12% by weight of said control releasing coat dry-weight.

38. (Original) The modified-release tablet of claim **37** wherein said plasticizer is selected from the group consisting of polyols, organic esters, oils/glycerides and any combination thereof.

39. (Original) The modified-release tablet of claim **38** wherein said plasticizer is a polyol.

40. (Original) The modified-release tablet of claim **39** wherein said polyol is polyethylene glycol 1450.

41. (Amended) The modified-release tablet of ~~any one of claims **28-40**~~ claim 28 wherein said water-soluble polymer is present from about 25% to about 50% by weight of said control-releasing coat dry weight.

42. (Original) The modified-release tablet of claim **41** wherein said water-soluble polymer is present at about 43% by weight of said control-releasing coat dry weight.

43. (Original) The modified-release tablet of claim **42** wherein said water-soluble polymer is selected from the group consisting of polyvinylpyrrolidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose and any combination thereof.

44. (Original) The modified-release tablet of claim **43** wherein said water-soluble polymer is polyvinylpyrrolidone.

45. (Amended) The modified-release tablet of ~~any one of claims **28-44**~~ claim 28 wherein the ratio of the water-insoluble water permeable film forming polymer:plasticizer:water-soluble polymer is from about 3:1:4 to about 5:1:3.

46. (Original) The modified-release tablet of claim **45** wherein the ratio of the water-insoluble water permeable film forming polymer:plasticizer:water-soluble polymer is about 4:1:3.

47. (Amended) The modified-release tablet of ~~any one of claims **28-44**~~ claim 28 wherein the ratio of the water-insoluble water-permeable film forming polymer: plasticizer:water-soluble polymer is from about 7:2:6 to about 19:5:18.

48. (Original) The modified-release tablet of claim **47** wherein the ratio of the water-insoluble water-permeable film forming polymer: plasticizer:water-soluble polymer is about 13:4:12.

49. (Original) The modified-release tablet of claim **28** wherein the weight gained after application of the control-releasing coat is from about 3% to about 30% of the weight of the dry core weight.

50. (Original) The modified-release tablet of claim **49** wherein the weight gained after application of the control-releasing coat is from about 13% to about 16% of the weight of the dry core weight.

51. (Original) The modified-release tablet of claim **50** wherein the weight gained after application of the control-releasing coat is from about 8% to about 10% of the weight of the dry core weight.

52. (Original) The modified-release tablet of claim **50** wherein the weight gained after application of the control-releasing coat is about 15% of the weight of the dry core weight.

53. (Original) The modified-release tablet of claim **51** wherein the weight gained after application of the control-releasing coat is about 9% of the weight of the dry core weight.

54. (Original) The modified-release tablet of claim **1** wherein said moisture barrier comprises an enteric polymer, a plasticizer and a permeation enhancer.

55. (Original) The modified-release tablet of claim **54** wherein said enteric polymer is present from about 30% to about 90% by weight of the moisture barrier dry weight.

56. (Original) The modified-release tablet of claim **55** wherein said enteric polymer is present at about 66% by weight of the moisture barrier dry weight.

57. (Original) The modified-release tablet of claim **56** wherein said enteric polymer is methacrylic acid copolymer type C.

58. (Original) The modified-release tablet of claim **57** wherein the polymer is Eudragit® L30 D-55.

59. (Original) The modified-release tablet of claim **54** wherein said plasticizer is present from about 1% to about 30% by weight of the moisture barrier dry weight.

60. (Original) The modified-release tablet of claim **59** wherein said plasticizer is present at about 10% by weight of the moisture barrier dry weight.

61. (Original) The modified-release tablet of claim **60** wherein said plasticizer is selected from the group consisting of polyols, organic esters, oils/glycerides and any combination thereof.

62. (Original) The modified-release tablet of claim **61** wherein said plasticizer is a combination of an organic ester and polyol.

63. (Original) The modified-release tablet of claim **62** wherein said plasticizer combination is in a proportion of about 1 part organic ester to about 2 parts polyol.

64. (Original) The modified-release tablet of claim **63** wherein said organic ester is triethyl ester and said polyol is polyethylene glycol 1450.

65. (Original) The modified-release tablet of claim **54** wherein said permeation enhancer is present from about 20% to about 40% by weight of the moisture barrier dry weight.

66. (Original) The modified-release tablet of claim **65** wherein said permeation enhancer is present at about 25% by weight of the moisture barrier dry weight.

67. (Original) The modified-release tablet of claim **66** wherein said permeation enhancer is selected from the group consisting of silicon dioxide, colloidal silicon, lactose, hydrophilic polymers, sodium chloride, aluminum oxide, colloidal aluminum oxide, silica, microcrystalline cellulose and any combination thereof.

68. (Original) The modified-release tablet of claim **67** wherein said permeation enhancer is silicon dioxide.

69. (Amended) The modified-release tablet of ~~any one of claims **54-68**~~ claim 54 wherein said enteric polymer, plasticizer and permeation enhancer is present in a ratio of about 13:2:5.

70. (Original) The modified-release tablet of claim **54** wherein the weight gained after application of the moisture barrier is no more than about 6% by weight of the tablet dry weight.

71. (Original) The modified-release tablet of claim **70** wherein the weight gained after application of the moisture barrier is no more than about 2.5% by weight of the tablet dry weight.

72. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of a pharmaceutically acceptable salt of bupropion, and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble, water-permeable film-forming polymer, a plasticizer and a water-soluble polymer; and

(iii) a moisture barrier surrounding said control-releasing coat, wherein said moisture barrier does not function as an enteric coating as defined by a USP test which requires for an enteric layer-coated tablet, when placed in 0.1N HCl for one hour, that the total amount of the drug released from the core does not exceed 10% and not less than 75% of the drug is released at 45 minutes in pH 6.8 buffer,

wherein the modified-release tablet is bioequivalent and exhibits a dissolution profile such that after about 2 hours no more than about 20% of the bupropion content is released, after about 4 hours about 15% to about 45% of the bupropion content is released, after about 8 hours about 40% to about 90% of the bupropion content is released and after about 16 hours no less than about 80% of the bupropion content is released.

73. (Original) The modified-release tablet of claim **72** wherein application of the moisture barrier to the control-releasing coated tablet results in a total weight gain of no more than about 6% relative to the dry tablet weight.

74. (Original) The modified-release tablet of claim **72** wherein application of the moisture barrier to the control-releasing coated tablet results in a total weight gain of no more than about 2.5% relative to the dry tablet weight.

75. (Original) The modified-release tablet of claim **72** wherein said moisture barrier is comprised of an enteric polymer, a plasticizer and a permeation enhancer.

76. (Original) The modified-release tablet of claim **75** wherein the enteric polymer is an acrylic polymer.

77. (Original) The modified-release tablet of claim **76** wherein said acrylic polymer is a methacrylic acid copolymer type C.

78. (Original) The modified-release tablet of claim **77** wherein said polymer is Eudragit® L30 D-55.

79. (Original) The modified-release tablet of claim **75**, which comprises about 150mg of said pharmaceutically acceptable salt of bupropion, and the amount of said enteric polymer ranges from 1% to 3% of the dry tablet weight and comprises 55% to 70% of the moisture barrier dry weight.

80. (Original) The modified-release tablet of claim **75**, which comprises about 300mg of said pharmaceutically acceptable salt of bupropion, and the amount of said enteric polymer ranges from 1.5% to 3.0% of the dry tablet weight and comprises from 30% to 90% of the moisture barrier dry weight.

81. (Original) The modified-release tablet of claim **80** wherein said enteric polymer is a methacrylic acid copolymer type C.

82. (Original) The modified-release tablet of claim **80** wherein said enteric polymer is a methacrylic acid copolymer type C.

83. (Original) The modified-release tablet of claim **81** wherein the polymer is Eudragit L 30 D-55.

84. (Original) The modified-release tablet of claim **82** wherein the polymer is Eudragit L 30 D-55.

85. (Original) The modified-release tablet of claim **72** wherein the moisture barrier comprises an enteric polymer, a plasticizer, and a permeation enhancer, wherein said enteric polymer is present at about 66% of the moisture barrier dry weight, said plasticizer is present at about 10% of the moisture barrier dry weight and said permeation enhancer is present at about 25% of the moisture barrier dry weight, and wherein the

weight gained after application of the moisture barrier is no more than about 2.5% by weight of the tablet dry weight.

86. (Original) The modified-release tablet of claim **85** wherein said tablet exhibits a dissolution profile such that after about 2 hours about 2% to about 18% of the bupropion content is released, after about 4 hours about 21% to about 37% of the bupropion content is released, after about 8 hours about 60% to about 85% of the bupropion content is released and after about 16 hours no less than about 93% of the bupropion content is released.

87. (Original) The modified-release tablet of claim **86** wherein said tablet exhibits a dissolution profile such that after about 2 hours about 4% to about 8% of the bupropion content is released, after about 4 hours about 28% to about 34% of the bupropion content is released, after about 8 hours about 68% to about 74% of the bupropion content is released and after about 16 hours no less than about 96% of the bupropion content is released.

88. (Original) The modified-release tablet of claim **87** wherein said tablet exhibits a dissolution profile such that after about 2 hours about 5% of the bupropion content is released, after about 4 hours about 32% of the bupropion content is released, after about 8 hours about 74% of the bupropion content is released and after about 16 hours no less than about 99% of the bupropion content is released.

89. (Original) The modified-release tablet of claim **72** wherein said pharmaceutically acceptable salt of bupropion is bupropion hydrochloride.

90. (Original) The modified-release tablet of claim **89** wherein said a pharmaceutically acceptable salt of bupropion is present at least at about 94% by weight of the core dry weight.

91. (Original) The modified-release tablet of claim **72** wherein said conventional excipients further comprise a binder and a lubricant.

92. (Original) The modified-release tablet of claim **91** wherein said binder is present from about 1% to about 6% by weight of the core dry weight.

93. (Original) The modified-release tablet of claim **92** wherein said binder is present at about 3% by weight of the core dry weight.

94. (Original) The modified-release tablet of claim **93** wherein said binder is selected from the group consisting of modified starch, gelatin, polyvinylpyrrolidone, cellulose derivatives, polyvinyl alcohol and any combination thereof.

95. (Original) The modified-release tablet of claim **94** wherein said binder is polyvinyl alcohol.

96. (Amended) The modified-release tablet of ~~any one of claims **91-95**~~ claim 91 wherein said lubricant is present from about 1% to about 6% by weight of the core dry weight.

97. (Original) The modified-release tablet of claim **96** wherein said lubricant is present at about 3% by weight of the core dry weight.

98. (Original) The modified-release tablet of claim **97** wherein said lubricant is selected from the group consisting of glyceryl behenate, stearic acid, hydrogenated vegetable oils and any combination thereof.

99. (Original) The modified-release tablet of claim **98** wherein said lubricant is glyceryl behenate.

100. (Original) The modified-release tablet of claim **72** wherein said water-insoluble water-permeable film forming polymer is present at about 35% to about 60% by weight of said control-releasing coat dry weight.

101. (Original) The modified -release tablet of claim **100** wherein said water-insoluble water-permeable film forming polymer is present at about 50% by weight of said control-releasing coat dry weight.

102. (Original) The modified-release tablet of claim **100** wherein said water-insoluble water-permeable film forming polymer is present at about 45% by weight of said control-releasing coat dry weight.

103. (Amended) The modified-release tablet of ~~any one of claims **100-102**~~ claim 100 wherein said water-insoluble water-permeable film forming polymer is selected from the group consisting of a cellulose ether, a cellulose ester, polyvinyl alcohol and any combination thereof.

104. (Original) The modified-release tablet of claim **103** wherein said water-insoluble water-permeable film forming polymer is a cellulose ether.

105. (Original) The modified-release tablet of claim **104** wherein said cellulose ether is selected from the group consisting of ethyl cellulose grade PR100, ethyl cellulose grade PR20 and any combination thereof.

106. (Original) The modified-release tablet of claim **105** wherein said cellulose ether is ethyl cellulose grade PR100.

107. (Original) The modified-release tablet of claim **72** wherein said plasticizer in said control-releasing coat is present from about 6% to about 30% by weight of said control-releasing coat dry weight.

108. (Original) The modified-release tablet of claim **107** wherein said plasticizer is said control-releasing coat is present at about 12% by weight of said control-releasing coat dry weight.

109. (Original) The modified-release tablet of claim **108** wherein said plasticizer is selected from the group consisting of polyols, organic esters, oils/glycerides and any combination thereof.

110. (Original) The modified-release tablet of claim **109** wherein said plasticizer is a polyol.

111. (Original) The modified-release tablet of claim **110** wherein said polyol is polyethylene glycol 1450.

112. (Original) The modified-release tablet of claim **72** wherein said water-soluble polymer is present from about 25% to about 50% by weight of said control-releasing coat dry weight.

113. (Original) The modified-release tablet of claim **112** wherein said water-soluble polymer is present at about 43% by weight of said control-releasing coat dry weight.

114. (Original) The modified-release tablet of claim **113** wherein said water-soluble polymer is selected from the group consisting of polyvinylpyrrolidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, and any combination thereof.

115. (Original) The modified-release tablet of claim **114** wherein said water-soluble polymer is polyvinylpyrrolidone.

116. (Original) The modified-release tablet of claim **72** wherein the weight gained after application of the control-releasing coat is from about 3% to about 30% of the weight of the dry core weight.

117. (Original) The modified-release tablet of claim **116** wherein the weight gained after application of the control-releasing coat is from about 13% to about 16% by weight of the dry core weight.

118. (Original) The modified-release tablet of claim **117** wherein the weight gained after application of the control-releasing coat is from about 8% to about 10% by weight of the dry core weight.

119. (Original) The modified-release tablet of claim **117** wherein the weight gained after application of the control-releasing coat is at about 15% by weight of the dry core weight.

120. (Original) The modified-release tablet of claim **118** wherein the weight gained after application of the control-releasing coat is at about 9% by weight of the dry core weight.

121. (Original) The modified-release tablet of claim **71** wherein said enteric polymer is methacrylic acid copolymer C.

122. (Original) The modified-release tablet of claim **121** wherein the polymer is Eudragit® L30 D-55.

123. (Original) The modified-release tablet of claim **75** wherein said plasticizer in said moisture barrier is selected from the group consisting of polyols, organic esters, oils/glycerides and any combination thereof.

124. (Original) The modified-release tablet of claim **123** wherein said plasticizer is a combination of an organic ester and polyol.

125. (Original) The modified-release tablet of claim **124** wherein said plasticizer combination is in a proportion of about 1 part organic ester to about 2 parts polyol.

126. (Original) The modified-release tablet of claim **125** wherein said organic ester is triethyl ester and said polyol is polyethylene glycol 1450.

127. (Original) The modified-release tablet of claim **75** wherein said permeation enhancer in said moisture barrier is selected from the group consisting of silicon dioxide, colloidal silicon, lactose, hydrophilic polymers, sodium chloride, aluminum oxide, colloidal aluminum oxide, silica, microcrystalline cellulose and any combination thereof.

128. (Original) The modified-release tablet of claim **127** wherein said permeation enhancer is silicon dioxide.

129. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride, polyvinyl alcohol, glyceryl behenate, wherein said bupropion hydrochloride is present at least at about 94% by weight of the core dry weight, said polyvinyl alcohol is present at about 3% by weight of the core dry weight, and said glyceryl behenate is present at about 3% by weight of each core dry weight;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising ethyl cellulose grade PR 100, polyethylene glycol 1450, and polyvinylpyrrolidone, wherein said ethyl cellulose grade PR 100 is present from about 45% to about 50% by weight of the control-releasing coating dry weight, said polyethylene glycol 1450 is present at about 12% by weight of the control-releasing coating dry weight, and said polyvinylpyrrolidone is present from about 25% to about 50% of the control-releasing coat dry weight, wherein the amount of said control-releasing coat applied is from about 9% to about 15% by weight of the dry tablet core; and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and

silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of 1 part triethyl citrate to 2 parts polyethylene glycol 1450, and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight, wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight;

wherein said modified-release tablet is bioequivalent and exhibits a dissolution profile such that after about 2 hours about 5% of the bupropion hydrochloride content is released, after about 4 hours, about 32% of the bupropion hydrochloride content is released, after about 8 hours, about 74% of the bupropion hydrochloride content is released and after about 16 hours no less than about 99% of the bupropion hydrochloride content is released.

130. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble, water-permeable film-forming polymer, a plasticizer and a water-soluble polymer; and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight, wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight,

wherein said modified-release tablet is bioequivalent and wherein said modified-release tablet when administered to a patient in need of such administration in the fasted

state provides a C_{max} of bupropion in the blood plasma at between about 3 hours and about 8 hours (T_{max}) after administration of the modified-release tablet.

131. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer; and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight,

wherein said modified-release tablet is bioequivalent and wherein said modified-release tablet when administered to a patient in need of such administration in the fasted state provides a C_{max} of bupropion in the blood plasma at about 5 hours (T_{max}) after administration of the modified-release tablet.

132. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer; and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and

silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight,

wherein said modified-release tablet is bioequivalent and wherein said modified-release tablet when administered to a patient in need of such administration in the fasted state provides a C_{max} of bupropion ranging from about 60 ng/ml to about 280 ng/ml in the blood plasma at about 5 hours (T_{max}) after administration of a once daily 300 mg dose of said modified-release bupropion hydrochloride tablet or a 2 x 150 mg dose once daily of said modified-release bupropion hydrochloride tablet.

133. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer; and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight,

wherein said modified-release tablet is bioequivalent and wherein said modified-release tablet when administered to a patient in need of such administration in the fasted

state exhibits a blood plasma concentration profile for bupropion as shown in Figure 3A after administration of a once daily 300 mg dose of said modified-release bupropion hydrochloride tablet or a 2 x 150 mg dose once daily of said modified-release bupropion hydrochloride tablet.

134. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble, water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight,

wherein said modified-release tablet is bioequivalent and wherein said modified-release tablet when administered to a patient in need of such administration in the fasted state exhibits an $AUC_{(0-t)}$ for bupropion from about 800 ng.hr/ml to about 2850 ng.hr/ml after administration of a once daily 300 mg dose of said modified-release bupropion hydrochloride tablet or a 2 x 150 mg dose once daily of said modified-release bupropion hydrochloride tablet.

135. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer; and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight, wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight,

wherein said modified-release tablet is bioequivalent and wherein said modified-release tablet when administered to a patient in need of such administration in the fasted state exhibits an $AUC_{(0\text{-}inf)}$ for bupropion from about 840 ng.hr/ml to about 3000 ng.hr/ml after administration of a once daily 300 mg dose of said modified-release bupropion hydrochloride tablet or a 2 x 150 mg dose once daily of said modified-release bupropion hydrochloride tablet.

136. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and

said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight, wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight,

wherein said modified-release tablet when administered as a 2 x 150 mg dose once daily or a 300 mg dose once daily to a patient in need of such administration in the fasted state is bioequivalent to Zyban®/Wellbutrin®SR.

137. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight, wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight;

wherein said modified-release tablet administered as a 2 x 150 mg dose once daily or a 300 mg dose administered once daily to a patient in need of such administration does not exhibit a food effect.

138. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of a pharmaceutically acceptable salt of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight, wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight;

wherein said modified-release tablet is bioequivalent and wherein a single dose of said modified-release tablet when administered to a patient in need of such administration in the fasted or fed state exhibits mean plasma concentration-time curves as shown in Figure 4A.

139. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight,

wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight,

wherein said modified-release tablet when administered as a 300 mg dose once daily to a patient in need of such administration in the fasted state is bioequivalent to Wellbutrin ® tablets administered 1 x 300 mg (t.i.d) at steady state.

140. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight, wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight,

wherein said modified-release tablet when administered as a 300 mg dose once daily to a patient in need of such administration in the fasted state is bioequivalent to Zyban® administered 1 x 150 mg twice daily (b.i.d.) at steady state.

141. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight, wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight,

wherein the moisture content is no more than about 0.4 % in said tablet when stored at 40°C ± 2°C/75%RH ± 5%RH in an open dish after about 10 days.

142. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight, wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight,

wherein said tablet contains at least about 95% undegraded bupropion hydrochloride after storage for 12 months at about 25°C ± 2°C/60%RH ± 5%RH.

143. (Original) The tablet of claim **142** wherein said tablet contains at least about 97% undegraded bupropion hydrochloride after storage for 12 months at about 25°C ± 2°C/60%RH ± 5%RH.

144. (Original) The tablet of claim **142** wherein said tablet contains at least about 98% undegraded bupropion hydrochloride after storage for 12 months at about 25°C ± 2°C/60%RH ± 5%RH.

145. (Original) The tablet of claim **142** wherein said tablet contains at least about 99% undegraded bupropion hydrochloride after storage for 12 months at about 25°C ± 2°C/60%RH ± 5%RH.

146. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight, wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight,

wherein the moisture content is no more than about 1% in said tablet when stored at 40°C ± 2°C/75%RH ± 5%RH after storage for about 6 months.

147. (Original) A modified-release tablet comprising:

(i) a core comprising an effective amount of bupropion hydrochloride and conventional excipients;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising, methacrylic acid copolymer, polyethylene glycol 1450, triethyl citrate and silicon dioxide, wherein said methacrylic acid copolymer is present at about 66% by weight of said moisture barrier dry weight, said polyethylene glycol 1450 and triethyl citrate is present at about 10% by weight of said moisture barrier dry weight in a proportion of about 1 part triethyl citrate to about 2 parts polyethylene glycol 1450 and said silicon dioxide is present at about 25% by weight of said moisture barrier dry weight, wherein the amount of the said moisture barrier applied is no more than about 2.5% of the tablet dry weight,

wherein said tablet contains at least about 95% undegraded bupropion hydrochloride after storage for 18 months at about 25°C ± 2°C/60%RH ± 5%RH.

148. (Original) The tablet of claim **147** wherein said tablet contains at least about 97% undegraded bupropion hydrochloride after storage for 18 months at about 25°C ± 2°C/60%RH ± 5%RH.

149. (Original) The tablet of claim **147** wherein said tablet contains at least about 98% undegraded bupropion hydrochloride after storage for 18 months at about 25°C ± 2°C/60%RH ± 5%RH.

150. (Original) The tablet of claim **147** wherein said tablet contains at least about 99% undegraded bupropion hydrochloride after storage for 18 months at about 25°C ± 2°C/60%RH ± 5%RH.

151. (Amended) The modified-release tablet of ~~claims 18, 30, 36, 41, 46, 52, 56, 60, 66, 69, 71, 90, 101, 108, 112, 119, or 141-150,~~ claim 18 wherein said tablet contains 150 mg of bupropion hydrochloride.

152. (Amended) The modified-release tablet of ~~claims 18, 31, 36, 42, 48, 53, 56, 60, 66, 69, 71, 90, 102, 108, 113, 120, or 141-150~~, claim 18 wherein said tablet contains 300 mg of bupropion hydrochloride.

153. (Original) A modified-release tablet comprising:

(i) a core comprising about 150 mg of bupropion hydrochloride, about 5.3 mg polyvinyl alcohol, about 4.7 mg glyceryl behenate;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising about 12 mg ethyl cellulose grade PR 100, about 3 mg polyethylene glycol 1450, and about 9 mg polyvinylpyrrolidone, wherein about 24 mg of the control releasing coat is applied onto said core; and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising about 4.6 mg methacrylic acid copolymer, about 0.46 mg polyethylene glycol 1450, about 0.23 mg triethyl citrate and about 1.72 mg silicon dioxide, wherein about 7 mg of the moisture barrier is applied onto the control releasing coated cores, and

wherein said modified-release tablet is bioequivalent and exhibits a dissolution profile such that after about 2 hours about 5% of the bupropion hydrochloride content is released, after about 4 hours, about 32% of the bupropion hydrochloride content is released, after about 8 hours, about 74% of the bupropion hydrochloride content is released and after about 16 hours no less than about 99% of the bupropion hydrochloride content is released.

154. (Original) A modified-release tablet comprising:

(i) a core comprising about 300 mg of bupropion hydrochloride, about 10.6 mg polyvinyl alcohol, about 9.4 mg glyceryl behenate;

(ii) a control-releasing coat surrounding said core, said control-releasing coat comprising about 13.1 mg ethyl cellulose grade PR 100, about 3.6 mg polyethylene

glycol 1450, and 12.4 mg polyvinylpyrrolidone, wherein about 29 mg of the control releasing coat is applied onto said core; and

(iii) a moisture barrier surrounding said control-releasing coat, said moisture barrier comprising about 6.9 mg methacrylic acid copolymer, about 0.7 mg polyethylene glycol 1450, 0.35 mg triethyl citrate and about 2.6 mg silicon dioxide, wherein about 10.5 mg of the moisture barrier is applied onto the control releasing coated cores, and

wherein said modified-release tablet is bioequivalent and exhibits a dissolution profile such that after about 2 hours about 5% of the bupropion hydrochloride content is released, after about 4 hours, about 32% of the bupropion hydrochloride content is released, after about 8 hours, about 74% of the bupropion hydrochloride content is released and after about 16 hours no less than about 99% of the bupropion hydrochloride content is released.